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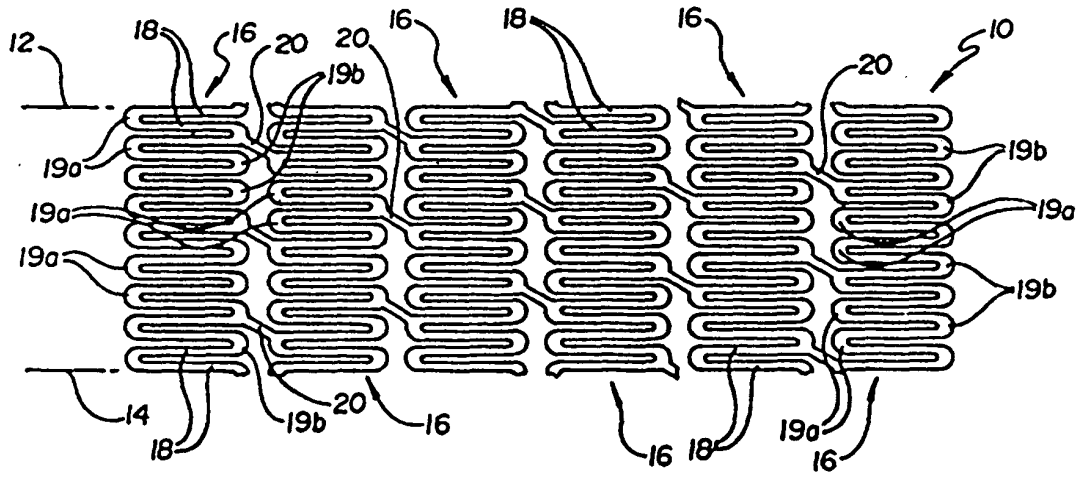
(54) Title: IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT



(57) Abstract

Segmented articulatable stent of open structure comprised of end-connected struts making up the segments with angular interconnects between segments.

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IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

This application is a Continuation of application Serial No. 08/396,569, filed March 1, 1995, the disclosure of which is hereby incorporated by reference.

Field of the Invention

This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular expandable stent of improved longitudinal flexibility.

Background of the Invention

Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

An example of the latter type is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

This invention is directed to stents of all these types when configured so as to be longitudinally flexible as described in detail hereinbelow. Flexibility is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known in the prior art. Examples are shown in U.S. Patent No. 4,856,516 to

Hillstead; U.S. Patent No. 5,104,404 to Wolff; U.S. Patent No. 4,994,071 to MacGregor; U.S. Patent No. 5,102,417 to Palmaz; U.S. Patent No. 5,195,984 to Schatz; U.S. Patent No. 5,135,536 to Hillstead; U.S. Patent 5,354,309 to Shepp-Pesch et al.; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

Generally speaking, these kinds of stents are articulated and are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact or on the outside of a bend the segments can move away from each other, leaving large gaps. This can lead to improper vessel support, vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross for devices to be installed through already implanted devices and to unsupported regions of vessel.

A diamond configuration with diagonal connections between each and every diamond of each segment is also known but such closed configurations lack flexibility.

It is an object of this invention to provide a longitudinally flexible stent of open configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally) in the stent body segments thereof rather than in flexible joints between the segments.

Summary of the Invention

To this end, the invention provides a tubular expandable stent, comprising: a plurality of cylindrical shaped open cylindrical segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating flexible pattern of interconnected substantially parallel struts with pairs thereof having alternating interconnecting end portions to define the periphery of the expandable stent segment, and in which the connected end portions of paired struts in each segment, before the

stent is expanded, are positioned substantially opposite to connected end portions of paired struts in adjacent segments. The segments are interconnected by a plurality of interconnecting elements extending from some of the connected end portions on one segment to some of the connected end portions on adjacent segments in such a manner that there are three or more legs between points of connection from one side of each segment to its other side. Additionally, the connecting elements extend angularly from connecting end portion of one segment to connecting end portion of an adjacent segment, not to an opposite connecting end portion on an adjacent segment, whereby upon expansion of the stent the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate flexing of the stent within paired struts without interference between adjacent segments, rather than by means of articulating flexible connectors between segments. As a result, the connectors between the segments are not intended to flex or bend under normal use.

Brief Description of the Figures

Figure 1 shows a flat view of an unexpanded stent configuration according to the invention.

Figure 2 shows the pattern of Figure 1 in a tubular, unexpanded stent.

Figure 3 shows an expanded stent of the configuration shown in Figure 1.

Figure 4 shows a flat view of an alternate unexpanded stent configuration according to the invention.

Best Mode Description of the Invention

Turning to the Figures, Figure 1 and Figure 2 show a fragmentary flat view of an unexpanded stent configuration and the actual tubular stent (unexpanded), respectively. That is, the stent is shown for clarity in Figure 1 in the flat and may be made from a flat pattern 10 (Figure 1) which is formed into a tubular shape by rolling the pattern so as to bring edges 12 and 14 together (Figure 1). The edges may then joined as by welding or the like to provide a configuration such as that shown in Figure 2.

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 16, each of which is formed in an undulating flexible pattern of substantially parallel struts 18. Pairs of struts are interconnected at alternating end portions 19a and 19b. As is seen in Figure 1, the interconnecting end portions 19b of one segment are positioned opposite interconnecting end portions 19a of adjacent segments. The end portions as shown are generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form 10 is formed into an unexpanded tube as shown in Figure 2, the segments are cylindrical but the end portions 19 of adjacent segments remain in an opposed position relative to each other.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate configuration.

Interconnecting elements 20 extend from one end portion 19 of one segment 16 to another end portion 19 of another adjacent segment 16 but not to an oppositely positioned end portion 19 of an adjacent segment 16. There are at least three struts included between the points on each side of a segment 16 at which an interconnecting element 20 contacts an end portion 19. This results in the interconnecting elements 20 extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements 20 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upwardly in one case and downwardly in another, although all connecting elements between any pair of segments are substantially parallel. Figure 1, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

As a result of this angular extension of the interconnecting elements 20 between adjacent segments and loops, upon expansion of the stent as seen in Figure 3, the closest adjacent end portions 19 between segments 16 are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments, i.e., pinching.

The number of interconnecting elements 20 may vary depending on circumstances in any particular instance. Three per segment are satisfactory for the configuration shown and at least three will be used typically.

The alternate design shown in Figure 4 includes longer struts 18a in the two end segments 16a than in the intermediate segments 16. This allows the end segments (16a) to have less compression resistance than the intermediate segments (16), providing a more gradual transition from the native vessel to the support structure of the stent. Otherwise, the configuration is the same as that shown in Figure 1.

As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may be of shape memory alloy such as Nitinol or the like, etc.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A tubular, flexible, expandable stent, comprising:

a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating pattern of interconnected substantially parallel struts to define the periphery of the expandable stent body, and in which adjacent pairs of struts in a given segment are interconnected at opposite ends, interconnected ends of one segment being positioned substantially opposite to interconnected ends of an adjacent segment, and

a plurality of interconnecting elements each extending from an end of paired struts on one segment to an end of paired struts on an adjacent segment, the elements extending angularly from one end on one segment to another end, not to an opposite end, on an adjacent segment, the distribution of the elements being such that there are at least three struts between each connecting point on opposite sides of the segments,

whereby, upon expansion of the stent, the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

2. The stent of claim 1 wherein the material of which it is comprised is metal.

3. The stent of claim 2 wherein the metal is a shape memory alloy.

4. The stent of claim 2 wherein the stent is a thin-walled tubular member.

5. The stent of claim 1 in a self-expanding configuration.

6. The stent of claim 1 in a mechanically expandable configuration.

7. The stent of claim 1 wherein the interconnecting elements between adjacent segments are of the same length.

8. The stent of claim 1 wherein the stent includes end segments and intermediate segments and the end segments of the stent include longer struts than the intermediate segments of the stent.

Fig. 1

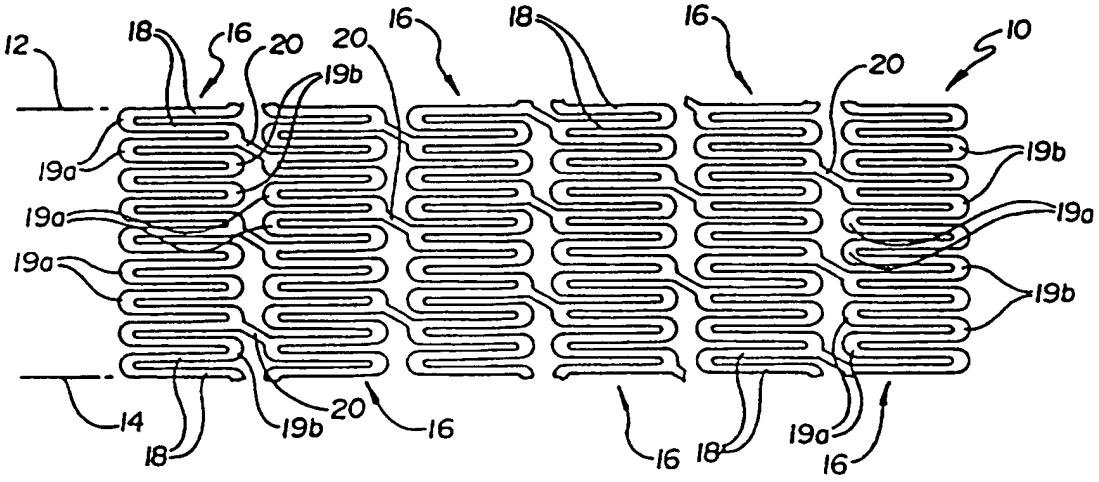
12
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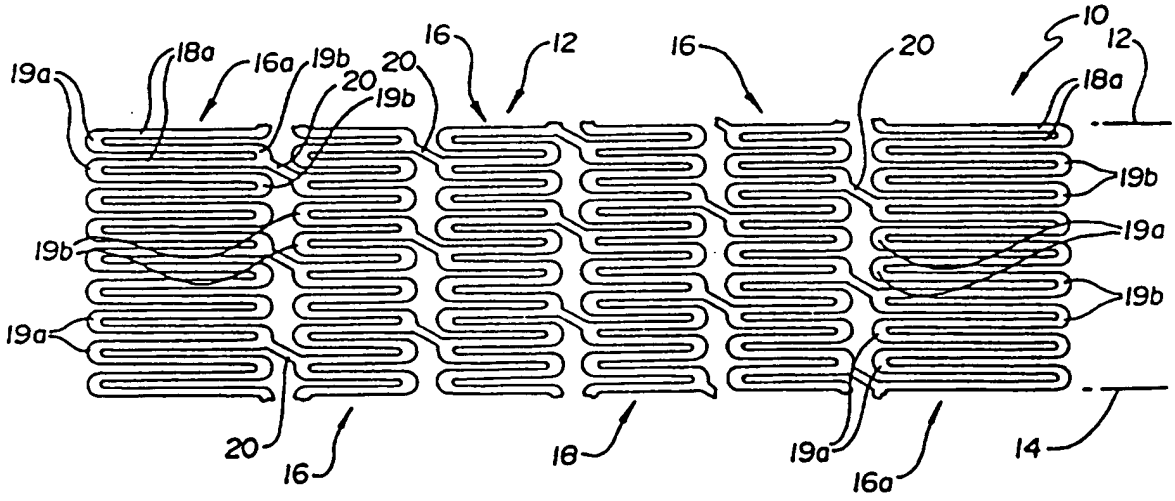
Fig. 4


19a
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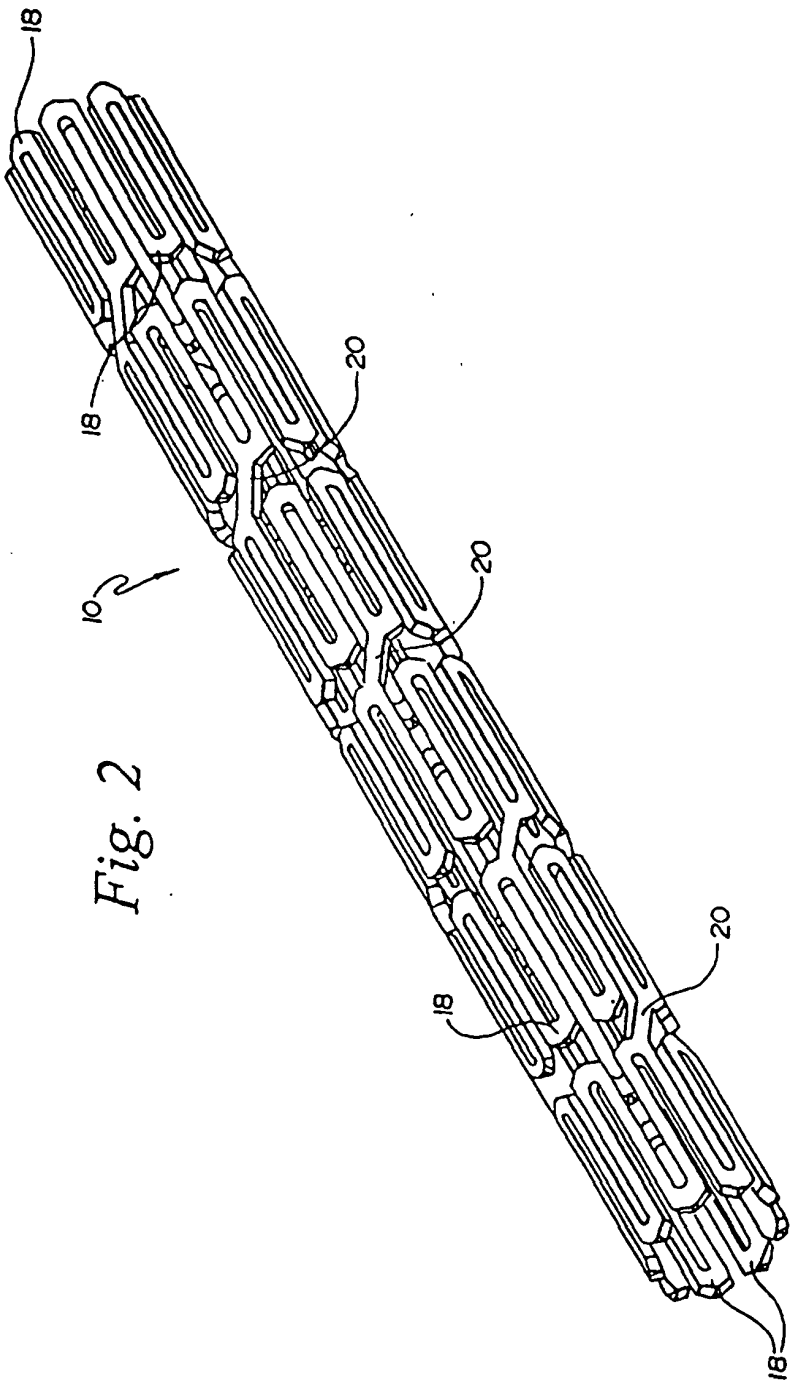

Fig. 2

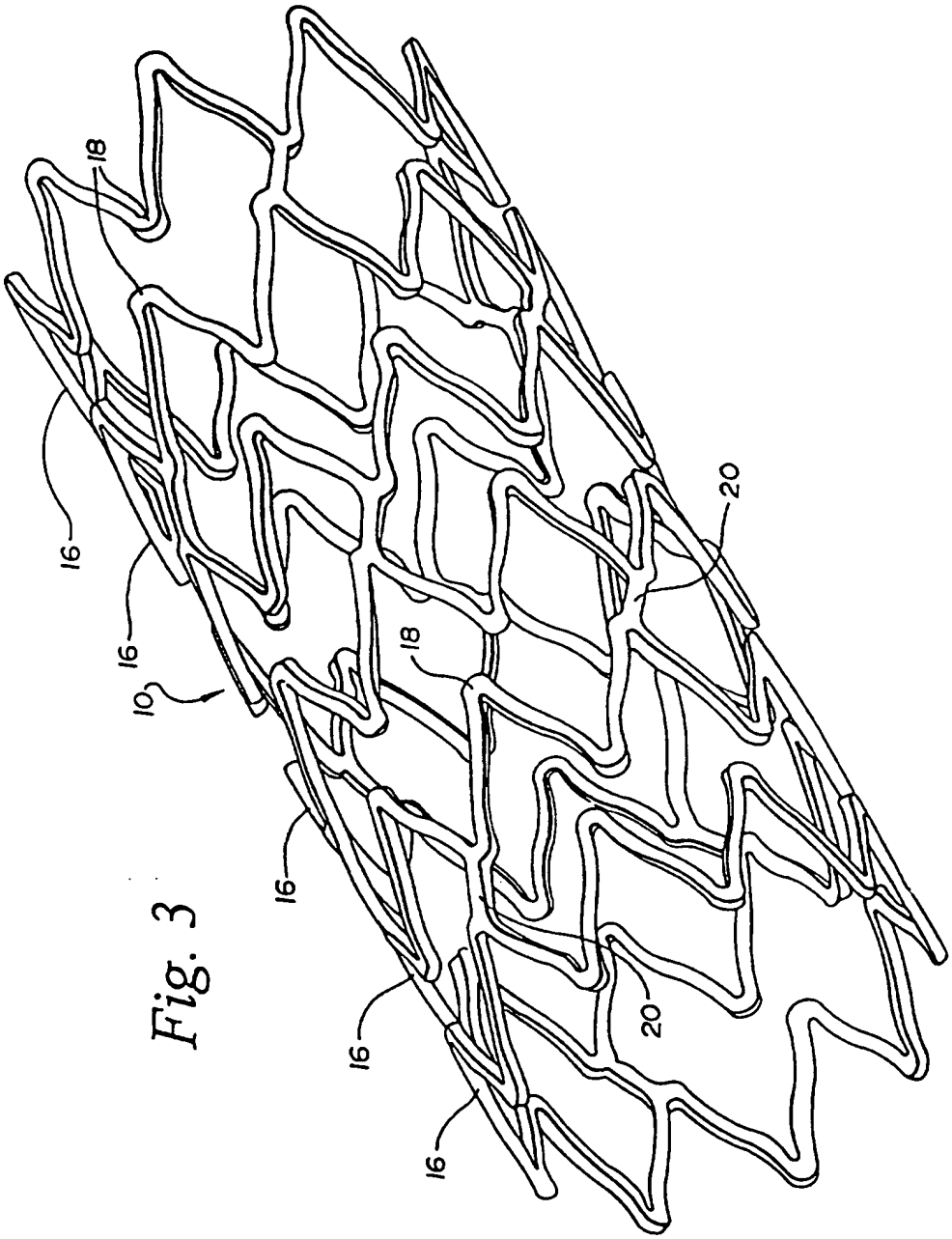

Fig. 3

INTERNATIONAL SEARCH REPORT

Inter ional application No.
PCT/US 96/02615

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/06 // A 61 B 17/12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

QUESTEL 2

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP, A2, 0540290 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.), 5 May 1993 (05.05.93), figures 4,5,11, abstract --	1-8
A	EP, A1, 0606165 (ETHICON INC.), 13 July 1994 (13.07.94), column 8, line 55 - column 9, line 20, figure 4 --	1-8
A	US, A, 5389106 (ALLEN J. TOWER), 14 February 1995 (14.02.95), figure 1, abstract -- --------	1-8

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing f the internati nal search report
19 June 1996	22. 07. 96
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INTERNATIONAL SEARCH REPORT

Information on patent family members

01/04/96

International application No.
PCT/US 96/02615

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A2- 0540290	05/05/93	CA-A- 2079417	29/04/93
		JP-A- 6181993	05/07/94
		US-A- 5421955	06/06/95
		US-A- 5514154	07/05/96
EP-A1- 0606165	13/07/94	NONE	
US-A- 5389106	14/02/95	WO-A- 9511720	04/05/95

Patentanwälte

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Anlage 1

Merkmalsanalyse von Anspruch 1

Stent zum Offenhalten eines Blutgefäßes, umfassend:

1. einen ersten eine Schlaufe enthaltenden Bereich (301e), wobei
   1.1 der erste eine Schlaufe enthaltende Bereich im Allgemeinen in der Umfangsrichtung angeordnet ist,
   1.2 die Schlaufen in dem ersten eine Schlaufe enthaltenden Bereich mit einer ersten Frequenz auftreten;
2. einen zweiten eine Schlaufe enthaltenden Bereich (301o), wobei
   2.1 der zweite eine Schlaufe enthaltende Bereich im Allgemeinen in der Umfangsrichtung angeordnet ist,
   2.2 die Schlaufen in dem zweiten eine Schlaufe enthaltenden Bereich ebenfalls mit der ersten Frequenz auftreten; und
3. einen dritten eine Schlaufe enthaltenden Bereich (513, 516, 519, 522, 525, 528),
   3.1 wobei die Schlaufen in dem dritten eine Schlaufe enthaltenden Bereich mit einer zweiten Frequenz auftreten, die höher ist als die erste Frequenz,
   3.2 der dritte Bereich in dem im Allgemeinen in Umfangsrichtung verlaufenden Raum zwischen den ersten und zweiten eine Schlaufe enthaltenden Bereichen angeordnet ist, und
   3.3 der dritte Bereiche alternierend mit den ersten und zweiten eine Schlaufe enthaltenden Bereichen verbunden ist.

VOSSIUS & PARTNER
Patentanwälte

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Anlage 2

Merkmalsanalyse von Anspruch 17

Stent zum Aufweiten eines Gefäßes in einem menschlichen Körper, umfassend:

1. eine Vielzahl von ersten Bändern (301e, 301) in Umfangsrichtung,
   1.1 beinhaltend ein Muster von Schlaufen mit einer ersten Frequenz;
2. eine Vielzahl von zweiten Bändern in Umfangsrichtung, die
   2.1 ein Muster von Schlaufen mit einer zweiten Frequenz beinhalten, die höher ist als die ersten Frequenz,
   2.2 mit den ersten Bändern in Umfangsrichtung abwechselnd sind, und
   2.3 periodisch an die ersten Bänder in Umfangsrichtung gekoppelt sind, um Zellen zu bilden.

Patentanwälte

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Anlage 3

Merkmalsanalyse von Anspruch 29

Ein expandierbarer Stent umfassend:

1. eine Vielzahl von eingeschlossenen, flexiblen Räumen, wobei jeder der Vielzahl von eingeschlossenen, flexiblen Räumen beinhaltet:
   - 1.1 ein erstes Element (501) mit einem ersten Ende (502) und einem zweiten Ende (503);
   - 1.2 ein zweites Element (504) mit einem ersten Ende (505) und einem zweiten Ende (506);
   - 1.3 ein drittes Element (507) mit einem ersten Ende (508) und einem zweiten Ende (509);
   - 1.4 ein viertes Element (510) mit einem ersten Ende (511) und einem zweiten Ende (512); wobei:
     - 1.4.1 das erste Ende (502) des ersten Elements mit dem ersten Ende (505) des zweiten Elements in Verbindung steht,
     - 1.4.2 das zweite Ende (506) des zweiten Elements mit dem zweiten Ende (509) des dritten Elements in Verbindung steht, und
     - 1.4.3 das erste Ende (508) des dritten Elements mit dem ersten Ende des vierten Elements (511) in Verbindung steht;
   - 1.5 ein fünftes Element (513) mit einem ersten Ende (514) und einem zweiten Ende (515);
   - 1.6 ein sechstes Element (516) mit einem ersten Ende (517) und einem zweiten Ende (518);
   - 1.7 ein siebtes Element (519) mit einem ersten Ende (520) und einem zweiten Ende (521);
   - 1.8 ein achtes Element (522) mit einem ersten Ende (523) und einem zweiten Ende (524);
   - 1.9 ein neuntes Element (525) mit einem ersten Ende (526) und einem zweiten Ende (527); und
   - 1.10 ein zehntes Element (528) mit einem ersten Ende (529) und einem zweiten Ende (530), wobei:
     - 1.10.1 das erste Ende (514) des fünften Elements mit dem zweiten Ende des ersten Elements (503) gekoppelt ist,
     - 1.10.2 das zweite Ende (515) des fünften Elements mit dem zweiten Ende (518) des sechsten Elements in Verbindung steht,
     - 1.10.3 das erste Ende (516) des sechsten Elements mit dem ersten Ende (519) des siebten Elements in Verbindung steht,

1.10.4 das zweite Ende des siebten Elements (521) mit dem zweiten Ende des achten Elements (524) in Verbindung steht,

1.10.5 das erste Ende (523) des achten Elements mit dem ersten Ende (526) des neunten Elements in Verbindung steht,

1.10.6 das zweite Ende (527) des neunten Elements mit dem zweiten Ende (530) des zehnten Elements in Verbindung steht, und

1.10.7 das erste Ende (529) des zehnten Elements mit dem zweiten Ende (512) des vierten Elements gekoppelt ist;

2. wobei das erste Element und das zweite Element mit dem gebogenen Abschnitt (535) an ihren Enden eine erste Schlaufe (530) bilden;
3. wobei das dritte und das vierte Element mit dem gebogenen Abschnitt (537) an ihren Enden eine zweite Schlaufe (531) bilden;
4. wobei das fünfte Element und das sechste Element mit dem gebogenen Abschnitt (539) an ihren Enden eine dritte Schlaufe bilden;
5. wobei das siebte Element und das achte Element mit dem gebogenen Abschnitt (540) an ihren Enden eine vierte Schlaufe bilden; und
6. das neunte Element und das zehnte Element mit dem gebogenen Abschnitt (451) an ihren Enden eine fünfte Schlaufe bilden.